

WE CLAIM:

1. A method for enhancing sexual desire and responsiveness in a female individual, comprising administering to the individual a therapeutically effective amount of an androgenic agent on an as-needed basis without regular dosing within the context of a chronic dosage regimen.

2. The method of claim 1, wherein the androgenic agent is contained within a pharmaceutical formulation.

3. The method of claim 2, wherein the pharmaceutical formulation is comprised of an immediate release dosage form, and the androgenic agent is administered about 0.25 to 72 hours prior to anticipated sexual activity.

4. The method of claim 3, wherein the androgenic agent is administered about 0.5 to 48 hours prior to anticipated sexual activity.

5. The method of claim 4, wherein the androgenic agent is administered about 1 to 24 hours prior to anticipated sexual activity.

6. The method of claim 5, wherein the androgenic agent is administered about 1 to 12 hours prior to anticipated sexual activity.

7. The method of claim 6, wherein the androgenic agent is administered about 1 to 4 hours prior to anticipated sexual activity.

8. The method of claim 2, wherein the pharmaceutical formulation is comprised of a sustained release dosage form.

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9. The method of claim 8, wherein following administration, the sustained release dosage form provides release of the androgenic agent over a drug delivery period in the range of about 4 to 72 hours.

5 10. The method of claim 9, wherein the drug delivery period is in the range of about 4 to 48 hours.

11. The method of claim 10, wherein the drug delivery period is in the range of about 4 to 24 hours.

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12. The method of claim 2 wherein the androgenic agent is selected from the group consisting of androsterone, androstenediol, androstenedione, ethylestrenol, oxandrolone, nandrolone, stanozolol, dromostanolone, testosterone, dehydroepiandrosterone, 4- dihydrotestosterone, methyl testosterone, testolactone, oxymetholone, fluoxymesterone, pharmacologically active salts and esters thereof, and combinations of any of the foregoing.

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13. The method of claim 12, wherein the androgenic agent is selected from the group consisting of testosterone, 4-dihydrotestosterone, and pharmacologically active esters thereof.

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14. The method of claim 13, wherein the androgenic agent is selected from the group consisting of testosterone and pharmacologically active esters thereof.

25 15. The method of claim 14, wherein the androgenic agent is testosterone.

16. The method of claim 14, wherein the androgenic agent is a pharmacologically active testosterone ester.

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17. The method of claim 15, wherein the testosterone ester is selected from the group consisting of testosterone enanthate, propionate, cypionate, phenylacetate, acetate, buccinate, heptanoate, decanoate, undecanoate, caprate, isocaprate, and C₄-C₆ alkyl-substituted cycloalkylcarboxylates.

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18. The method of claim 17, wherein the testosterone ester is testosterone propionate, testosterone undecanoate, testosterone C₄-C₆ alkyl-substituted cyclobutanecarboxylate, testosterone C₄-C₆ alkyl-substituted cyclopentanecarboxylates, and testosterone C₄-C₆ alkyl-substituted cyclohexanecarboxylates.

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19. The method of claim 12, wherein the androgenic agent is dehydroepiandrosterone.

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20. The method of claim 12, wherein the therapeutically effective amount is in the range of about 1 µg to about 250 mg.

21. The method of claim 20, wherein the therapeutically effective amount is in the range of about 1 µg to about 150 mg.

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22. The method of claim 21, wherein the therapeutically effective amount is in the range of about 10 µg to about 100 mg.

23. The method of claim 2, wherein the pharmaceutical formulation is administered to the patient's vulvar region and/or vagina.

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24. The method of claim 23, wherein the therapeutically effective amount is in the range of about 1 µg to about 100 mg.

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25. The method of claim 24, wherein the therapeutically effective amount is in the range of about 50 µg to about 50 mg.

5 26. The method of claim 25, wherein the therapeutically effective amount is in the range of about 1.0 mg to 25 mg .

27. The method of claim 23, wherein the pharmaceutical formulation is a topical formulation, and is administered to the patient's vulvar region.

10 28. The method of claim 23, wherein the pharmaceutical formulation is suitable for vaginal administration and is administered vaginally.

15 29. The method of claim 1, wherein administration is transdermal, sublingual, intranasal, buccal, rectal, parenteral, or by inhalation.

30. The method of claim 2, wherein the pharmaceutical formulation comprises a unit dosage form.

20 31. The method of claim 1, further comprising administering a therapeutically effective amount of at least one additional active agent.

32. The method of claim 31, wherein the at least one additional active agent is administered with the androgenic agent.

25 33. The method of claim 31, wherein the at least one additional active agent is administered prior to administration of the androgenic agent.

30 34. The method of claim 31, wherein the at least one additional active agent is administered after administration of the androgenic agent.

35. The method of claim 31, wherein the at least one additional active agent is a vasoactive agent.

36. The method of claim 35, wherein the vasoactive agent is a vasodilator.

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37. The method of claim 36, wherein the vasodilator is selected from the group consisting of vasoactive prostaglandins, endothelin-derived relaxation factors, vasoactive intestinal polypeptide agonists, smooth muscle relaxants, leukotriene inhibitors, and pharmacologically active salts, esters, prodrugs, and metabolites thereof, and combinations of any of the foregoing.

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38. The method of claim 37, wherein the vasodilator is a vasoactive prostaglandin.

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39. The method of claim 37, wherein the vasoactive prostaglandin is selected from the group consisting of naturally occurring prostaglandins, semisynthetic prostaglandins, synthetic prostaglandins, and pharmaceutically acceptable, pharmacologically active salts, esters, amides, inclusion complexes, prodrugs, metabolites, and analogs thereof, and combinations of any of the foregoing.

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40. The method of claim 39, wherein the vasoactive prostaglandin is selected from the group consisting of naturally occurring prostaglandins and hydrolyzable lower alkyl esters thereof.

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41. The method of claim 40, wherein the vasoactive prostaglandin is selected from the group consisting of PGE₀, PGE₁, 19-hydroxy-PGE₁, PGE₂, 19-hydroxy-PGE₂, PGA₁, 19-hydroxy-PGA₁, PGA₂, 19-hydroxy-PGA₂, PGB₁, 19-hydroxy-PGB₁, PGB₂, 19-hydroxy-PGB₂, PGB₃, PGD₂, PGF_{1α}, PGF_{2α}, PGE₃, PGF_{3α}, PGI₂, and hydrolyzable lower alkyl esters thereof.

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42. The method of claim 41, wherein the vasoactive prostaglandin is selected from the group consisting of PGE₀, PGE₁, PGE₂, and the methyl, ethyl and isopropyl esters thereof.

5 43. The method of claim 38, wherein the vasoactive prostaglandin is selected from the group consisting of arboprostil, carbaprostacyclin, carboprost tromethamine, dinoprost tromethamine, dinoprostone, enprostil, iloprost, lipoprost, gemeprost, metenoprost, sulprostone, tiaprost, viprostil, viprostil methyl ester, 16,16-dimethyl- Δ^2 -PGE₁ methyl ester, 15-deoxy-16-hydroxy-16-methyl-PGE₁ methyl ester, 16,16-dimethyl-PGE₁, 11-deoxy-15-methyl-PGE₁, 16-methyl-18,18,19,19-tetrahydro-carbacyclin, 16(RS)-15-deoxy-16-hydroxy-16-methyl-PGE₁ methyl ester, (+)-4,5-didehydro-16-phenoxy- α -tetranor-PGE₂ methyl ester, 11-deoxy-11 α ,16,16-trimethyl-PGE₂, (+)-11 α ,16 α ,16 β -dihydroxy-1,9-dioxo-1-(hydroxymethyl)-16-methyl-trans-prostene, 9-chloro-16,16-dimethyl-PGE₂, 16,16-dimethyl-PGE₂, 15(S)-15-methyl-PGE₂, 9-deoxy-9-methylene-16,16-dimethyl-PGE₂, potassium salt, 19(R)-hydroxy-PGE₂, 11-deoxy-16,16-dimethyl-PGE₂, and combinations thereof.

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44. The method of claim 38, wherein the therapeutically effective amount of the vasodilator is in the range of approximately 1 to 5000 μ g.

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45. The method of claim 44, wherein the therapeutically effective amount of the vasodilator is in the range of approximately 20 to 2000 μ g.

46. The method of claim 31, wherein the additional active agent is selected from the group consisting of rho kinase inhibitors, melanocortin peptides, endothelin antagonists, growth factors and other peptidyl drugs; selective androgen receptor modulators (SARMs), neuropeptides, amino acids, serotonin agonists, serotonin antagonists, calcium channel blockers, potassium channel openers, potassium channel blockers, dopamine agonists, dopamine antagonists, non-androgenic steroids, and combinations thereof.

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47. The method of claim 46, wherein the additional active agent is a dopamine agonist.

5 48. The method of claim 47, wherein the dopamine agonist is selected from the group consisting of levodopa, bromocriptine, pergolide, apomorphine, priribedil, pramipexole, ropinirole, and combinations thereof.

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10 49. A method for enhancing sexual desire and responsiveness in a female individual, comprising administering to the individual, approximately 0.25 to 72 hours prior to anticipated sexual activity, a therapeutically effective amount of an androgenic agent, followed by administration, approximately 0.25 to 24 hours prior to anticipated sexual activity, of a therapeutically effective amount of a prostaglandin.

15 50. A method for maintaining improving the tissue health of the female genitalia, comprising administering to a female individual, on an as-needed basis, a therapeutically effective amount of an androgenic agent.

20 51. A method for preventing vaginal atrophy, comprising administering to a female individual, on an as-needed basis, a therapeutically effective amount of an androgenic agent.

25 52. A method for preventing vaginal pain during sexual intercourse, comprising administering to a female individual suffering from dyspareunia a therapeutically effective amount of an androgenic agent, on an as-needed basis.

30 53. A method for alleviating vaginal itching and dryness, comprising administering to a female individual in need of such treatment a therapeutically effective amount of an androgenic agent, on an as-needed basis.

54. A method for enhancing sexual desire and responsiveness in a female individual, comprising administering an androgenic agent to the individual in an amount effective to provide a blood level of the agent or a metabolite thereof that approximates the blood level of the agent or a metabolite thereof during ovulation, wherein said
5 administering is on an as-needed basis without regular dosing within the context of a chronic dosage regimen.

55. A pharmaceutical formulation for enhancing female sexual desire and responsiveness, comprising (a) approximately 1.0 µg to 500 mg androgenic agent per
10 gram of formulation, (b) a pharmaceutically acceptable carrier suitable for vaginal and/or vulvar administration and selected to provide immediate release of the androgenic agent from the formulation following application to the individual's vagina and/or vulvar area, such that the formulation may be effectively administered on an on-demand basis.

56. The formulation of claim 58 wherein the androgenic agent is selected from the group consisting of androsterone, androstenediol, androstenedione, ethylestrenol, oxandrolone, nandrolone phenpropionate, nandrolone, stanozolol, dromostanolone, testosterone, dehydroepiandrosterone, 4-dihydrotestosterone, methyl testosterone, testolactone, oxymetholone, fluoxymesterone, pharmacologically active salts and esters
20 thereof, and combinations of any of the foregoing.

57. The formulation of claim 56, wherein the androgenic agent is selected from the group consisting of testosterone, 4-dihydrotestosterone, and pharmacologically active esters thereof.

58. The formulation of claim 57, wherein the androgenic agent is selected from the group consisting of testosterone and pharmacologically active esters thereof.

59. The formulation of claim 58, wherein the androgenic agent is testosterone.

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60. The formulation of claim 58, wherein the androgenic agent is a pharmacologically active testosterone ester.

5 61. The formulation of claim 58, containing approximately 1.0 μ g to 150 mg androgenic agent per gram of formulation

62. A packaged kit for a female individual to use in enhancing sexual desire and responsiveness, comprising: a pharmaceutical formulation of an androgenic agent; a container housing the pharmaceutical formulation during storage and prior to
10 administration; and instructions for carrying out drug administration to enhance sexual desire and responsiveness, on an as-needed basis.

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